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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,309	03/14/2006	Steve Leigh	032553-050	1503

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BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
ELLIS, SUEZU Y	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
01/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com
debra.hawkins@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/532,309	LEIGH ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/22/05,3/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 22, 2005 and March 14, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification fails to describe/define "ambient temperature" and also fails to support mixing above ambient temperatures in order to obtain dispersed particles below 1000 nm z average diameter, as recited in claims 9 and 20.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claim 6 is objected to because of the following informalities:

In clam 6, line 4 and claim 17, line 3, claim language recites "saturated fatty adds". It appears applicant intends "acids" instead of "adds". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for utilizing temperatures above 30°C (pg. 8, line 22) and provides examples utilizing a temperature above 50°C, does not reasonably provide enablement for mixing above ambient temperatures in order to obtain dispersed particles below 1000 nm z average diameter, as recited in claims 9 and 20. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

For examination purposes, claim language will be treated as "using a temperature above 30°C".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7, 9 and 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 3 and 14 recite the limitation "the dispersed particles". There is insufficient antecedent basis for this limitation in the claims. Claim 1 fails to explicitly recite "dispersed particles". Therefore it is unclear as to what applicant is referring to. Please clarify.

With respect to claim 3, it is unclear if the "at least one hydrogenated or partially hydrogenated membrane lipid" is the same as that recited in claim 1. If so, proper antecedent basis is needed. If not, better differentiation is needed.

Claims 4-6 and 15-17 recite the limitation "the dispersed phase". There is insufficient antecedent basis for this limitation in the claims. Claim 1 fails to explicitly recite "dispersed phase". Therefore it is unclear as to what applicant is referring to. Please clarify.

Claims 5 and 16 recite the limitation "hydrogenated/saturated". There is insufficient antecedent basis for this limitation in the claims. Further, it is unclear if the term means fully or partially hydrogenated or saturated. Please clarify. Claim language recites "hydrogenated/saturated diacyl membrane lipids with at least 70 mol % of saturated fatty acids". This phraseology is unclear. It is unclear if applicant means that (1) there is a second component, where the second component is present in at least 70

mol% and is a saturated fatty acid, or (2) that at least 70% of the "hydrogenated/saturated diacyl membrane lipids" is saturated with fatty acids, or (3) at least 70 mol % of all the fatty acids are completely saturated, or if there is an entirely different meaning. Please clarify.

With respect to claims 6 and 17, claim language recites "hydrogenated/saturated diacyl and monoacyl membrane lipids with at least 70% of saturated fatty acids". This phraseology is unclear. It is unclear if applicant means that (1) there is a second component, where the second component is present in at least 70% and being a saturated fatty acid, or (2) that the "hydrogenated/saturated diacyl and monoacyl membrane lipids" is at least 70% saturated, or (3) at least 70% of all the fatty acids are completely saturated, or if there is an entirely different meaning. It is unclear what the 70% of saturated fatty acids is with respect to. Please clarify.

With respect to claims 7, 9, 18 and 20, it is unclear what applicant means by "enzyme modified" or "enzyme modification" since applicant fails to specify in the claims the type of modification. Examiner notes that claim 1 recites "enzyme hydrolysis". Is the "enzyme modified" or "enzyme modification" the same as the "enzyme hydrolysis" recited in claim 1? If so, proper antecedent basis is needed.

With respect to claims 7 and 18, it is unclear if the monoacyl phosphatidylcholine is a product of the enzyme modification or if it is the lipid that is later modified. Please clarify.

With respect to claim 9 and 20, it is unclear what applicant considers "ambient temperature" to be since applicant does not provide support in the specification for the term. Applicant only discloses using a temperature above 30°C.

Claims not addressed are indefinite due to their dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Leigh et al. (WO 00/61113).

With respect to claim 1, Leigh et al. discloses a microdispersion comprising at least one hydrogenated or partially hydrogenated or saturated or partially saturated membrane lipid (pg. 8, lines 8-19) with enzyme hydrolysis (pg. 8, line 21-35) dispersed homogenously (pg. 13, lines 21-25) in a substantially non-aqueous and non-volatile hydrophilic medium (pg. 10, lines 22 - pg. 11, line 31).

With respect to claim 2, Leigh et al. discloses the dispersed particles are below 1000nm (pg. 5, lines 1-4).

With respect to claims 3 and 14, Leigh et al. discloses the dispersed particles include oil droplets comprising 10-30% by weight, thus between 0-40% by weight, of at least one oil associated with at least one hydrogenated or partially hydrogenated

membrane lipid with a particle size below 1000 nm z average diameter (pg. 7, lines 1-8; pg. 12, lines 1 and 6-8).

With respect to claims 4 and 15, Leigh et al. discloses the dispersed phase (hydrophilic medium) comprises 20-40% by weight of the overall composition, thus comprises 0.1-50% by weight of the total components (pg. 10, line 22).

With respect to claims 5-7 and 16-18, Leigh et al. discloses the dispersed phase (hydrophilic medium) comprises 0.01-40% by weight of diacyl membrane lipids and monoacyl membrane lipids (pg. 8, lines 8-19; pg. 7, lines 33-35; Example 1). Leigh et al. further discloses the acyl chain of the diacyl membrane lipids is saturated, thus is considered to have at least 70% saturated fatty acids (col. 8, lines 14-16).

With respect to claims 8 and 19, Leigh et al. discloses the non-aqueous hydrophilic medium comprises between 10-90% of glycerol (non-volatile liquid) (pg. 10, lines 22-30). Examiner notes that glycerol has a boiling point greater than 40°C.

With respect to claims 9 and 20, Example 1 demonstrates a step that involves dispersing at least one hydrogenated membrane lipid with enzyme modification (pg. 12, line 1) in a substantially non-aqueous hydrophilic medium (propylene glycol, glycerol) by using a temperature above 30°C (50°C) in order to obtain dispersed particles below 1000 nm z average diameter (pg. 19, line 12-13).

With respect to claims 10 and 11, Leigh et al. discloses the microdispersion is incorporated into a topical composition (pg. 17, line 35 – pg. 18, line 4).

With respect to claim 12, Leigh et al. discloses the microdispersion comprises biologically active compounds, excipients and preservatives (pg. 5, line 29; pg. 6, lines 6-10).

With respect to claim 13, Leigh et al. discloses microdispersions with enzyme hydrolysis (pg. 8, lines 33-34).

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600